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VIA ELECTRONIC FILING

Gary J. Buehler, R. Ph.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research
HFD-600
7519 Standish Place
Rockville, Maryland 20855

Re: Docket No. FDA-2010-N-0134

Dear Mr. Buehler:

We write on behalf of our client, Roxane Laboratories, Inc. ("Roxane"), in response to your request for comments regarding the expiration of U.S. Patent No. 5,608,075 ("Patent No. '075" or the "'075 Patent"), and its effect on the first applicant's eligibility for 180-day exclusivity for Cozaar® (Losartan Potassium) tablets and Hyzaar® (Losartan Potassium-hydrochlorothiazide) tablets (collectively "Losartan Products"). Since your request for comments, the Orange Book has been updated to reflect a March 4, 2009, expiration date for Patent No. '075. On expiration of the '075 Patent, all Paragraph IV certifications converted to Paragraph II certifications and became eligible for approval. *See Mylan Labs., Inc. v. Leavitt*, 484 F. Supp. 2d 109, 122 (D.D.C. 2007).[1] In addition, pursuant to 21 U.S.C. § 355(j)(5)(D)(i)(VI) and § (D)(ii), the expiration of Patent No. '075 forfeited the first applicant's right to 180-day exclusivity for the Losartan Products. Accordingly, Roxane's position is that under a correct reading of the law, the Food and Drug Administration ("FDA") should approve Roxane's ANDA for the Losartan Products without regard to any 180-day exclusivity period.

21 U.S.C. § 355(j)(5)(D)(i) and § (D)(ii) provide that a first applicant's right to 180-day exclusivity is forfeited when any of six "forfeiture events" occurs. Here, a "forfeiture event" occurred when "[a]ll of the patents to which the applicant submitted a certification qualifying it for the 180-day exclusivity period [ ] expired." 21 U.S.C.

[1] However, as required by 21 C.F.R. § 314.94(a)(12)(viii)(C)(1), Roxane intends to amend its certification from a Paragraph IV, to a Paragraph II, certification.

§ 355(j)(5)(D)(i)(VI).[2] Patent No. '075 was the only patent for which the first applicant submitted a Paragraph IV certification, and it expired on March 9, 2009, as a result of Merck's failure to pay maintenance fees to the United States Patent and Trademark Office ("USPTO"). In keeping with its decision to disclaim the '075 Patent in April 2005, Merck deliberately failed to pay its maintenance fees either when they were due, or during the six-month grace period that followed. *See* 35 U.S.C. § 41(b)(3). Reinstatement of an expired patent may occur, but only if the patent holder's conduct was either "unintentional" or "unavoidable." *See* 35 U.S.C. § 41(c)(1) (allowing reinstatement twenty-four months after the grace period if delay was "unintentional", or at any time after the grace period if delay was "unavoidable"). Having disclaimed the '075 Patent, Merck's conduct was neither "unintentional" nor "unavoidable", as those terms are interpreted by the USPTO. *See* The Manual of Patent Examining Procedure ("MPEP") § 711.03, subsection II.C.1 (stating "deliberately chosen course of conduct cannot be considered as 'unintentional'")[3]; *id.* at 2590, subsection I (the delay in payment of the maintenance fee at issue is not "unavoidable", "where the record fails to disclose that the patentee took reasonable steps, or discloses that the patentee took no steps, to ensure timely payment of the maintenance fee"). As a result, Merck may not reinstate the expired '075 Patent.

In sum, the '075 Patent has expired, and the 180-day exclusivity period is forfeited pursuant to 21 U.S.C. § 355(j)(5)(D)(ii). **In addition, because Roxane is converting its Paragraph IV certifications to Paragraph II certifications, Teva is not entitled to exclusivity.** We do not believe that the D.C. Circuit's opinion in *Teva Pharm., Inc. v. Sebelius*, No. 09-5281 (D.C. Cir. March 2, 2010) alters this conclusion. **That opinion addressed a separate and discrete forfeiture event under 21 U.S.C. § 355(j)(5)(D)(i) – the delisting of the '075 Patent – and has no bearing on whether the expiration of the '075 Patent caused the 180-day exclusivity to be forfeited.**

Roxane is aware that on March 16, 2010, the United States District Court for the District of Columbia enjoined FDA from approving ANDAs for various Losartan products, including Roxane's. Roxane believes that this order is incorrect as a matter of law and goes beyond the scope of the D.C. Circuit's opinion in *Teva Pharm., Inc. v.*

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[2] In 2003, Congress amended the Hatch-Waxman Act via the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") to include the forfeiture provisions discussed above. Before and after 2003, FDA consistently interpreted the Hatch-Waxman Act as not allowing 180-day exclusivity to survive patent expiration, and courts upheld this interpretation as reasonable. *E.g.*, *Mylan Labs., Inc. v. Leavitt*, 484 F. Supp. 2d 109, 122-23 (D.D.C. 2007); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 354 (D.N.J. 2003).

[3] Under the MPEP, this standard applies both to patents that have expired due to non-payment of maintenance fees and patent applications that have been abandoned. *See* MPEP 2590, subsection I.

Sebelius. Nevertheless, Roxane requests that FDA issue a decision regarding its Losartan ANDAs and, in particular, if the agency believes that it does not have authority to approve Roxane's ANDA that it immediately issue such a decision, so that Roxane may seek judicial review of the agency's action.

Please feel free to contact us if you have any questions.

Sincerely,

William B. Schultz/AWM

William B. Schultz
Alexandra W. Miller

ATTORNEYS FOR ROXANE
LABORATORIES, INC.